Summary of Food and Drug Import Safety Act of 2007
(Changes from Discussion Draft denoted in bold)

Section 2: Research on Testing Techniques for Use in Inspections of Imported Food Safety; Priority Regarding Detection of Intentional Adulteration

- Amends Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) by adding a new section (p) entitled Research on Testing Techniques for Use in Inspection for Imported Food Safety.

- Requires the Secretary to provide research on testing techniques and sampling methods for use of inspections on food.

- Priority shall be given to research that:

    1) Is conducted for the development of tests that are suitable for inspections at U.S. ports of entry.

    2) Development of tests that would help detect intentionally adulterated food.

- Requires reports every six months on how the current research is moving towards the ultimate goal of rapid tests that can detect intentionally adulterated food.

Section 3: Imported Food Inspection User Fees

- Amends Chapter VIII of the Federal Food, Drug, and Cosmetic Act by adding Section 801A.

- Requires the Secretary to assess and collect user fees on food imported into the United States. Fees will go directly towards import inspections, lab testing on import samples, and research on testing techniques for intentionally adulterated food imports.

- Not less than 90 percent of the fees shall be used for inspections.

- Not more than 10 percent of the fees shall be used for research.

- Fee is assessed on each line item of food, and may not exceed $50 per line.

- Secretary granted authority to waive or reduce fee where the Secretary finds the fee to be paid will exceed the present and future costs incurred in carrying out inspections.

- **Fees may be used for to pay for overseas inspections with respect to food by the Department of Health and Human Services.**

Section 4: Imported Drug Inspection User Fees

- Amends Chapter VIII of the Federal Food, Drug, and Cosmetic Act by adding Section 801B.

- Requires the Secretary to assess and collect user fees on drugs imported into the United States. Priority is given to spending fees on inspection conducted at ports of entry into the United States, laboratory tests on import samples, with the greatest priority given to the inspections and tests to detect the intentional adulteration or misbranding of drugs.

- Fee is assessed on each line item of drugs, and shall not exceed $1000 per line item.

- Secretary granted authority to waive or reduce fee where the Secretary finds the fee to be paid will exceed the present and future costs incurred in carrying out inspections.

- **Fees may be used to pay for overseas inspections with respect to drugs by the Department of Health and Human Services.**

Section 5: Authority to Restrict Food Importation to Specific Ports of Entry

- Amends Section 801 of the Federal Food, Drug, and Cosmetic Act.

- The Secretary shall restrict the importation of food to ports of entry that are located in a metropolitan area with a Food and Drug Administration laboratory.

- The Secretary may waive this requirement that the importation of such food through such port will not increase the probability that such food will cause serious, adverse health consequences or death; [and/or] there is a reasonable probability that the type of food will not cause serious, adverse health consequences or death

- The Secretary shall transition to such a system within 5 years of enactment.

Section 6: Country of Origin Labeling

- Amends Chapter IV of the Federal Food, Drug, and Cosmetic Act by adding a new Section 417.

- **The Secretary shall promulgate regulations within 180 days of enactment to require the labeling of foods, drugs, and devices to identify the country of origin of foods, drugs, and devices.**

Section 7: Safe and Secure Food Importation Program

- Amends Chapter VIII of the Federal Food, Drug, and Cosmetic Act by adding a new Section 805.

- Not later than 2 years after the date of enactment, the Secretary shall create a voluntary program for companies that import food and agree to abide by specific food safety and security guidelines to receive expedited movement of that company's food through the inspection process.

- Factors that the Secretary shall take into account include:

1) The company's personnel importing the food;

2) The physical and procedural safety and security of a company's food supply chain;

3) Sufficiency of access controls for food and ingredients purchased by a company;

4) Need for tracking and maintaining records on food and ingredients purchased by such a person or moved through the supply chain;

5) Documentation processing through a company's supply chain;

6) Access by the Secretary to a company's business records for review; and

7) A company's vendor and supplier information.

Section 8: Enhanced Civil Monetary Penalties

- Amends Section 303 of the Federal Food, Drug, and Cosmetic Act.

- Increases civil penalties for manufacturers or importers that violate the Act. Penalties are raised to $100,000 in the case of an individual, $500,000 in the case of a company introducing or delivery, not to exceed $1 million for all adjudications in a single proceeding.

Section 9: Continued Operation of Field Laboratories

- Bars the Secretary from terminating or consolidating any of the current 13 FDA field laboratories.

- Bars the Secretary from terminating or consolidating any of the current 20 FDA district offices or any of the inspection or compliance functions of any of the 20 district offices.

- In preparing any reorganization plan, the Secretary shall consult with personnel and unions to be affected by the plan.

- Once published, the Secretary must submit a report detailing the Food and Drug Administration field organization to the Comptroller General, the Committee on Energy and Commerce, and the Senate Committee on Health, Education, Labor, and Pensions.

- Government Accountability Office shall study the cost effectiveness of such a plan and its impact on food, drug, and other products regulated by FDA. GAO shall provide the study to the Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions.

- Within 180 days of receipt of the GAO study, Congress may disapprove of the field organization plan.

Section 10: Recall Authority

- Amends Chapter IV of the Federal Food, Drug, and Cosmetic Act by adding a new Section 417.

- If the Secretary finds that there is a reasonable probability that a food would cause serious, adverse health consequences or death, the Secretary may issue an order requiring the appropriate person to cease distribution.

- Within 10 days of the order to cease distribution, the person has the opportunity for an informal hearing on the actions required by the order and on whether the order should be amended to require a recall.

- After providing an opportunity for an informal hearing, the Secretary may determine to amend the order to require a recall. The Secretary will determine a timetable in which the food recall will occur and requires periodic reporting describing the recall progress.

- Recall authority does not include recall of a food from individuals.

Section 11: Inspection and Other Standards; Applicability, Enforcement; Certifications

- Amends Chapter IV of the Federal Food, Drug, and Cosmetic Act by adding a new Section 418.

- All food intended for consumption that is offered for importation into the United States would be subject to the same standards applied to such food in the United States.

- Any food intended for consumption that does not **appear to** meet all the standards referred to in subsection (a) shall not be permitted entry into the United States.

- The Secretary will enforce this provision through appropriate random inspections, sampling, and testing.

- **No food shall be permitted entry into the United States from a foreign facility in a foreign country unless there is: (1) a certification for such facility; or (2) a certification for such country where a facility is located.**

- Each foreign facility from which food is imported into the United States **may** obtain a certification issued by the Secretary stating that the facility maintains a program using reliable analytical methods to ensure compliance with all U.S. standards.

- **A foreign country may obtain a certification by the Secretary stating that (1) the country has in effect and is enforcing food safety standards at least as protective of food safety as the standards applicable to food and (2) the country has a program in effect to monitor and enforce its food safety standards with respect to food being exported from such country to the United States.**

- The Secretary shall revoke any foreign facility's **or a foreign country's certification** should the Secretary deem that the facility **or foreign country** is not maintaining a program that uses reliable analytical methods to ensure compliance with all U.S. standards.

- The review of any such certification, by the Secretary, may include the inspection of foreign facilities to ensure that the inspection program of the foreign facility involved is meeting such standards.

Section 12: Regulations on Adequate Testing of Processed Food

- Amends Chapter IV of the Federal Food, Drug, and Cosmetic Act by adding a new Section 419.
- Within 2 years of enactment, the Secretary shall require, by regulation, that as good manufacturing practices, processed food undergo testing to detect substances in the food that may render the food adulterated.
- Review of test results must be provided to the Secretary upon demand.

Section 13: Records of Interstate Shipment

- Amends subsection (a) of section 703 of the Federal Food, Drug, and Cosmetic Act.
- Strikes "upon the request" and inserts "upon the written or oral request".
- Strikes the following language from Section 703 of the Federal Food, Drug, and Cosmetic Act: **"**except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers, except as provided in subsection (b) of this section."

Section 14: Labeling Requirement for Meat, Poultry Products, and Seafood that Contain Carbon Monoxide

- Meat, poultry or seafood intended for human consumption that includes carbon monoxide to affect coloring shall bear a label that is prominently and conspicuously displayed for the ordinary person to understand.
- The label shall state: "SAFETY NOTICE: Carbon monoxide has been used to preserve the color of this product. Do not rely on color or the "use or freeze by" date alone to judge the freshness or safety of the product. Discard any product with an unpleasant odor, slime, or a bulging package."
- It shall go into effect 30 days after enactment of the legislation.
- After 5 years, the Secretary has the discretion to issue alternative labeling requirements that are shown to be adequate and effective in preventing consumer deception and other harms related to the conditions of use of carbon monoxide.